



Narcotic Treatment Program Manual

A Guide to DEA Narcotic Treatment Program Regulations

Revised 2022

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This Narcotic Treatment Program Manual has been prepared by the Drug Enforcement Administration, Diversion Control Division, as a guide to assist narcotic treatment programs (NTPs) in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the narcotic addiction treatment profession.

The 2022 edition replaces all previous editions of the NTP Manual issued by the Drug Enforcement Administration, both hard copy and electronic.

Guidance documents, like this document, are not binding and lack the force and effect of law, unless expressly authorized by statute or expressly incorporated into a contract, grant, or cooperative agreement.

Message from the Assistant Administrator

The Drug Enforcement Administration (DEA) is pleased to provide you with the 2022 edition of the Narcotic Treatment Program Manual (NTP Manual) to assist you in understanding the provisions of the Controlled Substances Act (CSA). This NTP Manual will answer questions you may encounter and provide guidance in complying with the CSA and DEA regulations. This edition has been updated to include information on the Drug Addiction Treatment Act of 2000 (DATA), the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016 (CARA), and the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act of 2018 (SUPPORT Act).

The role of each NTP in the proper handling of controlled substances is critical to the health of patients and helps protect society against drug abuse and diversion. Your compliance with the CSA and DEA regulations will greatly help to protect the public health, ensure patient safety, and prevent the diversion of controlled substances.

Sincerely,

 Digitally signed by
KRISTI O'MALLEY
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Abbreviations

CARA	Comprehensive Addiction and Recovery Act of 2016
CFR	Code of Federal Regulations
CSA	Controlled Substances Act
CSAT	Center for Substance Abuse Treatment
DATA	Drug Addiction Treatment Act of 2000
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
LTCF	Long Term Care Facility
MAT	Medication-Assisted Treatment for Opioid Use Disorders
NTP	Narcotic Treatment Program
OTP	Opioid Treatment Program
OD	Opioid Use Disorder
SAMHSA	Substance Abuse and Mental Health Services Administration
SOTA	State Opioid Treatment Authority
SUPPORT Act	Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act of 2018
UIN	Unique Identification Number
U.S.	United States
U.S.C.	United States Code

1. Introduction

This manual is intended to summarize and explain the basic requirements for administering and dispensing (but not prescribing) narcotic controlled substances approved by the Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment in a DEA registered NTP under [subchapter I \(Control and Enforcement\) of the CSA](#) and DEA regulations, [21 CFR Parts 1300 to End](#).

1.1 Disclaimer

This NTP Manual is **not** a legal document. It is a guidance document that provides statutory and regulatory requirements as well as recommended practices. Statutory and regulatory requirements use language such as “must,” “shall,” or “required” and will include statutory and/or regulatory citation(s). Recommended practices in this NTP Manual are voluntary and use language such as “should” or “recommend” to identify these suggestions. Readers should refer to the most current copy of the [CSA](#) and the Code of Federal Regulations ([CFR](#)) to obtain the most complete and accurate up-to-date statutory and regulatory information. These publications are available on the DEA Diversion Control Division website Publication and Manuals webpage. Should any pertinent provisions of the law or regulations be modified in the future, DEA will issue a revised electronic version of this document, which will be posted on DEA’s Diversion Control Division website at www.DEAdiversion.usdoj.gov.

If there are errors in this manual, please send notification to the following: ODLP@dea.gov or

Drug Enforcement Administration
Policy Section (DPY)
8701 Morrisette Drive
Springfield, VA 22152

Inquiries regarding topics within this manual may be addressed to the local [DEA Diversion Field Office or the address above](#).

Printed copies of the complete regulations implementing the CSA (21 CFR Part 1300 to end) may be obtained from:

Superintendent of Documents
U.S. Government Publishing Office
Washington, DC 20402

Both the CFR and the Federal Register (which includes proposed and final rules implementing the CSA) are available on the internet through the U.S. Government Publishing Office website. This website, which provides information by section, citation, and keywords, can be accessed at:

<https://www.govinfo.gov>

Copies of pertinent CFR citations and this NTP Manual may be found on the internet on DEA’s Diversion Control Division website at www.DEAdiversion.usdoj.gov

1.2 Authorization for Public Dissemination

All material in this manual is in the public domain and may be reproduced without the express permission of DEA.

1.3 Preface

The CSA, which consolidated numerous drug laws and established a single system of control for both narcotics and psychotropics, is the legal foundation of the United States Government's fight against the abuse of drugs and other substances. Currently, the CSA regulates, among other things, the manufacture, distribution, and dispensing of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances.

In 1973, DEA was established to serve as the single federal agency to consolidate and coordinate the government's drug control activities. DEA's Diversion Control Division carries out the mandates of the CSA by preventing the diversion of pharmaceutical controlled substances and listed chemicals into the illicit market while ensuring an adequate and uninterrupted supply is available to meet the country's legitimate medical, commercial, and scientific needs.

Under the framework of the CSA, all controlled substance transactions take place within a "closed system" of distribution established by Congress. Within this closed system, all legitimate handlers of controlled substances – including NTPs – must be registered with DEA (unless exempt) and maintain strict accounting for all controlled substance transactions. [21 U.S.C. 822](#), [823\(g\)\(1\)](#), and [827](#); and [21 CFR 1301.11\(a\)](#), [1304.03\(a\)](#), and [1304.21](#).

It is important to highlight the laws that amended the CSA regarding the use of controlled substances in the medical treatment of narcotic dependent patients. The Narcotic Addiction Treatment Act mandated that practitioners who dispense narcotic drugs to individuals for maintenance or detoxification treatment must obtain annually a separate DEA registration. The DATA amended the CSA by waiving the separate registration requirement if the practitioner is qualified to treat narcotic dependence with certain schedule III-V narcotic controlled substances approved by FDA for that indication. These practitioners were previously referred to as DATA-Waived Physicians or qualifying physicians, but are currently referred to as "Qualifying Practitioners." The CARA and SUPPORT Act expanded the DEA registered entities who may treat patients under the DATA (i.e., physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, or certified nurse midwives) also known as Qualifying Other Practitioners. For additional information regarding narcotic addiction treatment requirements for Qualifying Practitioners and Qualifying Other Practitioners, see the "Drug Abuse Treatment Act 2000 Qualifying Practitioner Manual, A Guide to DEA Qualifying Practitioner and Qualifying Other Practitioner Regulations" on DEA's Diversion Control Division website at www.DEAdiversion.usdoj.gov on the Publications and Manuals webpage.

The Department of Health and Human Services (HHS) issued an Interim Final Rule, in 2003, amending the federal opioid treatment program regulations by adding buprenorphine and buprenorphine combination products to the list of approved opioid treatment medications that may be used in federally certified and registered opioid treatment programs, SAMHSA.gov.

It should be noted that the CSA (21 U.S.C. 802) defines and uses the terms "maintenance treatment" and "detoxification treatment" – treatments that involve the dispensing of a narcotic

drug¹ for a certain time period and purpose – whereas DEA regulations (21 CFR 1300.01(b)) use the term “narcotic treatment program.” DEA is aware that other government agencies in the addiction treatment community commonly use “medication-assisted treatment for opioid addiction” instead of “narcotic treatment” and “opioid treatment program” instead of “narcotic treatment program.” *For the purposes of this manual, these terms are interchangeable.*

Federal controlled substances laws are designed to function in tandem with state controlled substances laws. DEA works in cooperation with state professional licensing boards and state and local law enforcement officials to ensure that pharmaceutical controlled substances are prescribed, administered, and dispensed for legitimate medical purposes in accordance with federal and state laws.

Some states have additional requirements beyond those mandated by federal law. NTPs must comply with all requirements established by both state and federal governments. While this manual explains the federal DEA regulatory requirements, NTPs should also consult with their respective State Opioid Treatment Authority ([SOTA](#)), or equivalent, to ensure compliance with state laws and regulations.

DEA and the drug addiction treatment profession have a common interest in the appropriate use of controlled substances. DEA’s goal is to maintain a positive working relationship with all of its registrants, including NTPs. DEA understands it can best serve the public interest by working with the registrant community to prevent the diversion of licit pharmaceutical controlled substances into the illicit market.

2. Registration Requirements for NTPs

This section addresses the steps for the DEA initial registration and renewal for NTPs. NTPs must annually renew their registration. [21 U.S.C. 823\(g\)\(1\)](#) and [21 CFR 1301.11\(a\)](#) and [1301.13\(e\)\(1\)\(vii\)](#).

2.1 Initial Registration

A separate DEA registration is required to administer or dispense (but not prescribe) to narcotic dependent persons those narcotic drugs which have been approved specifically for use in maintenance or detoxification treatment. [21 CFR 1306.07\(a\)](#). In addition to obtaining this separate DEA registration, this type of activity also requires the approval and certification by the Substance Abuse and Mental Health Services Administration (SAMHSA) as well as [state authority](#). [21 U.S.C. 823\(f\) and 823\(g\)\(1\)](#), [21 CFR 1306.07\(a\)](#), [42 CFR 8.11](#). If a person owns and operates more than one NTP, each place of business must be separately registered with DEA. [21 CFR 1301.12\(a\)](#).

An NTP application is limited to schedule II and III narcotics approved by FDA specifically for the treatment of narcotic addiction. To register with DEA as an NTP, the applicant must apply using DEA Form 363 (Application for Registration Under the Narcotic Addict Treatment Act of 1974), which must be completed online at www.DEAdiversion.usdoj.gov. [21 CFR 1301.13\(e\)\(1\)\(vii\)](#). The form includes complete instructions and the cost of the application fee.

¹ Narcotic drug is defined under [21 U.S.C. 802\(17\)](#) and [21 CFR 1300.01\(b\)](#).

The registration application requires a business (DEA registered address) and a mailing address. These addresses do not have to be the same. The business address that is printed on DEA Form 223 (Certificate of Registration) is the principal place of business or professional practice of the NTP where controlled substances are manufactured, distributed, or dispensed by the NTP based on its DEA registration. The business location is considered a “controlled premises.”

[21 CFR 1316.02\(c\)](#). All required records, as well as the DEA Form 223 and any stocks of controlled substances, must be kept at this address. [21 CFR 1301.35\(c\)](#) and [1316.02\(c\)](#), and [21 CFR Part 1304](#). **DEA has the authority to enter a controlled premises to conduct an unscheduled on-site administrative inspection.** (See Appendix B of this manual and [21 U.S.C. 880](#).)

DEA will send correspondence to the mailing address provided on the NTP application. The mailing address provided can be the same as the physical location of the NTP’s business address or an alternative address, such as a corporate address or post office box. However, the mailing address, if different from the business address, will not be printed on the DEA Form 223 or on the DEA Form 222 (U.S. Official Order Forms – Schedule I & II). **An NTP will not receive controlled substances at its mailing address if it differs from the NTP’s business address.**

2.2 NTP Registration Business Activities

DEA uses six business activities to identify the type of narcotic treatment(s) that an NTP may provide:

- Maintenance
- Detoxification
- Maintenance and Detoxification
- Compounder/Maintenance
- Compounder/Detoxification
- Compounder/Maintenance and Detoxification

2.3 Approval Process

Once DEA receives a new application, the local [DEA Diversion Field Office](#) contacts the NTP to schedule an on-site, pre-registration investigation. During the investigation, DEA personnel explain recordkeeping and security requirements. The NTP’s security systems are tested and evaluated for compliance. This pre-registrant investigation includes verification of state licensure with [SOTA](#) and certification by SAMHSA.

Upon approval, a DEA Form 223 is issued and mailed to the mailing address indicated on the application. The DEA Form 223 must be maintained at the NTP’s registered location in a readily retrievable manner and available for official inspection. [21 CFR 1301.35\(c\)](#).

An NTP may not order, store, or dispense any controlled substances until an application is approved and is assigned a DEA registration number. [21 CFR 1301.13\(a\)](#). A separate registration is required for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed. [21 CFR 1301.12\(a\)](#).

An NTP can obtain a duplicate DEA Form 223 in the following ways:

- [Download](#) from DEA’s Diversion Control Division website;

- Contact DEA Headquarters' Registration Section at 800-882-9539;
- E-mail a request to DEA.Registration.Help@dea.gov; or,
- Contact the local [DEA Registration Program Specialist](#).

An NTP DEA Form 223 is valid for 12 months. However, some programs may receive an initial registration period of less or more than 12 months. A detailed explanation for this occurrence can be found at [21 CFR 1301.13\(c\)](#).

In addition, an NTP must take an initial inventory, which is an actual physical count of all controlled substances on hand on the date the NTP first engages in the manufacture, distribution, or dispensing of controlled substances, as applicable. [21 CFR 1304.11\(b\)](#). (See Section 4 of this manual.)

2.4 Modification of DEA Registration

A DEA registration can be modified at any time. Modifications can include a change of business and/or mailing address, name change, a change of drug schedules, or a request to become an authorized collector. There is no fee for a modification of registration. Modification requests require DEA approval. [21 CFR 1301.51](#). This request can be made [online](#) or by contacting the NTP's local [DEA Registration Program Specialist](#) in writing.

Every registrant under 21 U.S.C. 801 – 904 shall be required to report any change of professional or business address in accordance with DEA regulations. [21 U.S.C. 827\(h\)](#).

When an NTP moves or changes its address, it is first necessary to request a modification of registration. Modifications are handled in the same manner as applications and must be approved by DEA. [21 CFR 1301.51\(a\), \(c\)](#). The request must contain the registrant's name, address, and registration number as printed on the Certificate of Registration (DEA Form 223); the new name or address; and a signature in accordance with [21 CFR 1301.13\(j\)](#). If the change of address involves a change in state, the proper state issued license and SAMHSA certification should be obtained prior to approval of the modification of the federal registration. [DEA](#) recommends that the request be made at least 60 days in advance of the anticipated relocation.

As is the case with new applications, DEA will not approve the change of address of the NTP without the proper authorizations from the [SOTA](#) and SAMHSA. If the modification is approved, DEA will issue a new DEA Form 223 and, if requested, new DEA Form 222s with the new address. The new registration certificate must be maintained with the old registration certificate until expiration. [21 CFR 1301.51\(c\)](#) and [1301.35\(c\)](#).

It is important to remember that an NTP cannot order, possess, or dispense any controlled substances at a new facility until DEA approves the modification and the address has been changed on the DEA registration certificate. The new certificate can be downloaded [online](#) after DEA has approved the modification.

Any NTP that intends to administer or dispense (but not prescribe) FDA-approved schedule III narcotic controlled substances for the treatment of narcotic addiction must request to amend the DEA NTP registration to include schedule III narcotic controlled substances. [21 CFR 1301.51\(a\)](#)

An NTP registrant can go [online](#) and request that schedule III narcotic drugs be added to the NTP's registration. [21 CFR 1301.51\(a\), \(c\)](#). Alternatively, this request can be made in writing

to the local [DEA Registration Program Specialist](#) responsible for the area in which the NTP is located.

For the disposal of patients' medications, an NTP can apply to modify its DEA registration to become an authorized collector by submitting an online request to www.DEAdiversion.usdoj.gov. [21 CFR 1301.51\(b\)](#) and [1317.40](#). (See [Section 13.6](#) of this manual.)

2.5 Renewal of DEA Registration

A DEA registration for an NTP must be renewed every year utilizing DEA Form 363a (Renewal Application for DEA Registration). [21 CFR 1301.13\(e\)\(1\)\(vii\)](#). The renewal must be completed [online](#) not more than 60 days before the expiration date. [21 CFR 1301.13\(b\)](#). The information from the existing DEA Form 223 is needed to [login to initiate the renewal process](#). The cost of the application fee is indicated on the application.

Registrants will begin to receive renewal notifications approximately 60 days prior to the expiration date. [21 CFR 1301.13\(e\)\(3\)](#). DEA no longer sends renewal notifications by U.S. Postal Service. Instead, an electronic reminder to renew is sent at 60, 45, 30, 15, and 5 days prior to the expiration date of the registration to the associated email address. It is important for a registrant to update the email address associated with a registration to ensure delivery of electronic reminders.

The following policy and procedures with respect to [renewal and reinstatement of a DEA registration](#) is as follows:

- If a **renewal application** is submitted in a timely manner **prior to expiration**, the practitioner may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application. [21 CFR 1301.36\(i\)](#).
- DEA policy allows the reinstatement of an **expired registration** for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances for any period of time under an expired registration. *Cf.* [21 CFR 1301.13](#) (requiring that no person shall engage in any controlled substance activity until an application for registration or reregistration for that activity is granted).

Furthermore, the Administrator may extend any other existing registration under the circumstances contemplated in 21 CFR 1301.36 even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety. [21 CFR 1301.36\(i\)](#).

For additional information or questions, contact DEA's Registration Section at 1-800-882-9539 or DEA.Registration.Help@dea.gov.

2.6 Termination of Registration

An NTP that discontinues business activities either completely or only regarding controlled substances must return its DEA Form 223 and unused DEA Form 222s to the local [DEA Registration Program Specialist](#), [21 CFR 1301.52\(c\)](#). In addition, DEA may ask for the location where inventories and other required controlled substance records will be stored during the requisite two-year retention period. It is also recommended that the NTP notify the local [DEA Diversion Field Office](#) as far in advance of the actual closing date as possible.

Unwanted controlled substances in the NTP's possession must be disposed of in accordance with [21 CFR part 1317](#) prior to surrendering the DEA registration. (See Section 11 of this manual.)

2.7 Transfer of Controlled Substances Upon Discontinuance of Business

Pursuant to [21 CFR 1301.52\(d\)](#), an NTP registrant that desires to transfer its business operations to another NTP registrant must submit in person or by registered or certified mail, return receipt requested, to the Special Agent in Charge in his or her area, at least 14 days in advance of the date of the proposed transfer (unless the Special Agent in Charge waives this time limitation in individual instances), the following information:

1. The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor);
2. The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);
3. Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed); and
4. The date on which the transfer of controlled substances will occur.

On the day the controlled substances are transferred, a complete inventory must be taken in accordance with [21 CFR 1304.11](#) which documents the drug name, dosage form, drug strength, quantity, and date transferred. [21 CFR 1301.52\(e\)\(1\)](#). In addition, DEA Form 222 or the electronic equivalent must be prepared to document the transfer of schedule II controlled substances. [21 CFR 1301.52\(e\)\(1\)](#) and [1305.03](#). This inventory will serve as the final inventory for the registrant going out of business and transferring the controlled substances. It will also serve as the initial inventory for the registrant acquiring the controlled substances. A copy of the inventory must be included in the records of each NTP. It is not necessary to send a copy of the inventory to DEA. [21 CFR 1301.52\(e\)\(1\)](#). The pharmacy acquiring the controlled substances must maintain all records involved in the transfer of the controlled substances for two years. [21 U.S.C. 827\(b\)](#) and [21 CFR 1304.04\(a\)](#).

All controlled substance records required to be kept by the registrant-transferor shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee. [21 CFR 1301.52\(e\)\(2\)](#).

2.8 Denial, Suspension, or Revocation of Registration

Under the CSA ([21 U.S.C. 824\(a\)](#)), DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that the registrant has:

- Materially falsified any application filed pursuant to or required by the CSA;
- Been convicted of a felony relating to a controlled substance or a list I chemical under the CSA or any other law of the United States, or of any State;
- Had his/her State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;
- Failed to comply with any standard referred to in [21 U.S.C. 823\(g\)\(1\)](#). *See also Turning Tide, Inc.*, 81 FR 47,411 (2016); or
- Been excluded (or directed to be excluded) from participation in a program pursuant to [42 U.S.C. 1320a-7\(a\)](#).

The Attorney General may, in his discretion, suspend any registration granted simultaneously with the institution of proceedings under [21 U.S.C. 824](#), in cases where he finds that there is an imminent danger to public health and safety. A failure to comply with a standard referred to in [21 U.S.C. 823\(g\)\(1\)](#) may be treated as grounds for immediate suspension. “Imminent danger to the public health or safety” means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligation under subchapters I and II, there is substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration. [21 U.S.C. 824\(d\)](#).

2.9 Medication Unit

“Medication unit” is a facility that has been established as part of, but is geographically separate from, an opioid treatment program from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis. [42 CFR 8.2](#). Medication units can be located at a hospital, community pharmacy, practitioner’s office, or correctional facility. Activities of a medication unit are performed in accordance with all pertinent state laws and regulations. [42 CFR 8.11\(i\)\(1\)](#).

The medication unit is required to have a separate DEA registration as an NTP. [21 CFR 1301.12\(a\)](#). DEA will verify the medication unit’s [SOTA](#) and SAMHSA authorization prior to approval. Medication units also are required to maintain separate inventories, records, reports, and security in accordance with DEA regulations. [21 CFR 1304.03\(a\)](#) and [1301.71-1301.74](#).

At the medication unit, licensed private practitioners or community pharmacists can only dispense or administer FDA-approved narcotic drugs for maintenance and detoxification, or collect samples for drug testing or analysis. As DEA registered NTPs, medication units are

prohibited from prescribing approved narcotic controlled substances (e.g., methadone, buprenorphine, and buprenorphine combination products) under an affiliated NTP registration. [21 CFR 1306.07\(a\)](#).

To open a medication unit, the affiliated NTP should also contact SAMHSA ([SAMHSA.gov](#)) and its [State Opioid Treatment Authority \(SOTA\)](#) regarding those agencies' requirements

2.10 Emergency Rule for a Physician Not Registered as an NTP

According to [21 CFR 1306.07\(b\)](#), no provisions in section 1306.07 prohibit a DEA-registered physician, who is not specifically registered with DEA to conduct an NTP, from administering (but not prescribing) narcotic drugs to a person to relieve their acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. In these cases, the physician may only administer a single day's treatment at one time. This emergency treatment may not extend for more than three days and cannot be renewed or extended beyond this time period.

3. Recordkeeping Requirements for NTPs

All controlled substance records must be maintained for two years for inspection and duplication by authorized DEA employees. [21 U.S.C. 827\(b\)](#) and [21 CFR 1304.04\(a\)](#). Records and inventories of schedule II controlled substances must be maintained separately from all other records of the NTP. All records and inventories of schedule III-V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records. [21 CFR 1304.04\(f\)](#).

Every NTP registrant must maintain complete and accurate records on a current basis for each controlled substance manufactured, procured, received, stored, distributed, dispensed, or otherwise disposed of. [21 CFR 1304.21\(a\)](#). Separate records must be maintained by a registrant for each independent activity for which he or she is registered or authorized. [21 CFR 1304.21\(c\)](#).

3.1 Recordkeeping and Patient Confidentiality

Each NTP must have a recordkeeping system that can document patient care and is able to maintain patient confidentiality as required under [21 CFR 1304.24\(d\)](#), except that such records may be disclosed for purposes and under the circumstances authorized by [42 CFR Part 2](#). NTPs must comply with all recordkeeping and reporting requirements for state, local, and federal laws that are relevant for the treatment of narcotic addiction. (See Section 7 of this manual.)

DEA recommends, but does not require, that NTPs record and review whether a patient is enrolled at another NTP.

3.2 Required Records

Each NTP must maintain patient records in a dispensing log in accordance with [21 CFR 1304.24](#) containing the following information:

- Name, strength, and dosage form of substance;
- Date dispensed;

- Adequate identification of patient (consumer);
- Amount consumed;
- Amount and dosage form taken home by patient; and,
- Dispenser's initials.

NTPs that compound narcotics drugs for offsite use at other NTPs must maintain records as outlined in [21 CFR 1304.25](#). (See [Section 10.2](#) of this manual.) The table below lists the required records, the related DEA Form, and the CFR reference line.

Description	DEA Form Number	CFR Reference (link)
Official Order Form for Schedule I and II Controlled Substances	DEA Form 222	21 CFR 1305.17(a) and (c), 1305.12(e), 1305.20
Reports of Theft or Significant Loss	DEA Form 106	21 CFR 1301.74(c)
Inventory of Drugs Surrendered for Disposal	DEA Form 41	21 CFR 1304.21(e)
DEA Certificate of Registration	DEA Form 223	21 CFR 1301.35(c)
Power of Attorney authorization to sign DEA Form 222		21 CFR 1305.05
Receipts and/or invoices for schedules III, IV, and V narcotic controlled substances		21 CFR 1304.04
All inventory records of controlled substances, including the initial and/or biennial inventories, dated and marked as of beginning or close of business		21 CFR 1304.11
Records of controlled substances distributed (sales to other registrants, transfers between NTPs, returns to vendors, distributions to reverse distributors, etc.)		21 CFR 1304.21
Records of controlled substances administered and dispensed		21 CFR 1304.24(a) and (b)
Records of breakage and/or spillage		21 CFR 1317.05
Authorization to accept delivery of controlled substances ordered		21 CFR 1301.74(h)

3.3 Central Recordkeeping

If an NTP desires to maintain shipping and financial records **other than** executed DEA Form 222s and inventories, at a central location rather than at its registered location, the NTP must submit written notification of its intention by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge where an NTP is located. See the local [DEA Diversion Field Office](#). The NTP may begin maintaining central records 14 days after DEA receives this notification unless informed by DEA that permission has been denied. [21 CFR 1304.04\(a\)\(1\)](#).

Registrants must abide by federal and state laws and regulations pertaining to controlled substance recordkeeping requirements. Nothing in DEA's regulations authorizes or permits "any person to do any act which such person is not authorized or permitted to do under other Federal laws or... under the law of the State in which he/she desires to do such act nor shall compliance ... be construed as compliance with other Federal or State laws unless expressly provided in such other laws." [21 CFR 1307.02](#).

4. Inventory Requirements for NTPs

This section reviews DEA regulations for maintaining an inventory of all controlled substances utilized by the NTP.

4.1 Inventory Requirements

An inventory is a complete and accurate physical count of all stocks and forms of controlled substances in an NTP's possession. See [21 CFR 1304.11\(a\)](#). All inventories must be maintained at the registered location in a readily retrievable manner for two years for inspection by DEA. In addition, inventory records of schedule II controlled substances must be kept separate from all other controlled substance records. [21 CFR 1304.04\(a\), \(f\)\(1\)](#). The inventory records of schedules III, IV, and V shall be maintained either separately from all other records of the NTP or in such form that the information required is readily retrievable from the ordinary business records of the NTP. [21 CFR 1304.04\(f\)\(2\)](#). All inventories must be marked and identified as having been taken either at the opening or close of business on the respective inventory date. [21 CFR 1304.11\(a\)](#).

DEA recommends, but does not require, that an inventory includes the NTP's name, address, DEA registration number, and the signature of the person(s) responsible for taking the inventory.

4.2 Initial Inventory

An inventory of all stocks of controlled substances on hand must be taken on the date the NTP first engages in the manufacture, distribution, or dispensing of controlled substances. [21 U.S.C. 827\(a\)\(1\)](#) and [21 CFR 1304.11\(b\)](#). If there are no stocks of controlled substances on hand when business commences, the registrant must record as a zero inventory on the initial inventory. [21 CFR 1304.11\(b\)](#). There is no requirement to submit a copy of the inventory to DEA. In accordance with [21 CFR 1304.11\(a\), \(b\), and \(e\)\(6\)](#), the inventory must include the following information:

- The date the inventory was taken;
- The time of day the inventory was taken (i.e., at the open or close of business);
- The name of each controlled substance inventoried;
- The finished form of each substance (e.g., 10 mg tablet);
- The number of dosage units or volume of each finished form in the commercial container (e.g., 100 tablet bottle or 3 mL vials);
- The number of commercial containers of each finished form (e.g., four 100 tablet bottles); and
- A total count of the substances.

If the substance is listed in schedule II, an exact count or measure of the contents is required. If the substance is listed in schedule III-V, an estimated count or measure of the contents is acceptable, unless the container holds more than 1,000 tablets or capsules, in which case, an exact count of the contents is required.

4.3 Biennial Inventory

After the initial inventory is taken, a new inventory of all stocks of controlled substances on hand must be taken at least once every two years. [21 U.S.C. 827\(a\)\(1\)](#) and [21 CFR 1304.11\(c\)](#). The biennial inventory requires the same information as the initial inventory (as noted in the section 4.2 list). The biennial inventory may be taken on any date within two years of the previous inventory date. [21 CFR 1304.11\(c\)](#). There is no requirement to submit a copy of the inventory to DEA.

4.4 Newly Scheduled Controlled Substance Inventory

When a drug not previously listed as a controlled substance is scheduled, all stocks of the drug on hand must be inventoried as of the effective date of scheduling by the registrant. [21 U.S.C. 827\(a\)\(2\)](#), [21 CFR 1304.11\(d\)](#).

5. Ordering Schedule II Controlled Substances

The DEA Form 222 or the electronic equivalent is required for each distribution or procurement of a schedule II controlled substance (electronic ordering is addressed later in this section), [21 CFR 1305.03](#). An NTP is required to order schedule II controlled substances using the DEA Form 222.

On September 30, 2019, DEA issued a final rule entitled [*New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances*](#) (DEA Form 222), which implemented a new format for the form used by DEA registrants to order schedule I and II controlled substances. 84 FR 51368. The rule became effective on October 30, 2019, and included a “sunset date”- a date after which use of the triplicate forms would not be allowed – of October 30, 2021. All subsequent references to DEA Form 222 in this manual are for single-sheet forms.

5.1.1 Requesting DEA Forms 222

DEA Forms 222 are issued in mailing envelopes containing a predetermined number of forms based on the business activity of the registrant, each form consisting of one single-sheet. A limit, which is based on the business activity of the registrant, will be imposed on the number of DEA Forms 222 that will be furnished upon a requisition for order forms unless additional forms are specifically requested and a reasonable need for such additional forms is shown. [21 CFR 1305.11\(a\)](#).

Unexecuted DEA Forms 222 can be requested initially by checking the block in “Section 3” on the DEA Form 363, which may be found [online](#).

Any person with an active registration that is authorized to order schedule I and II controlled substances is entitled to obtain a DEA Form 222, which will be supplied at any time after the

DEA registration is granted. Any person holding a registration authorizing the person to obtain a DEA Form 222 may requisition the forms [online](#) through a [DEA secured network connection](#) or by contacting any [Division Office](#) or the Registration Section of the Administration through the [customer service center](#). [21 CFR 1305.11\(b\)](#).

Each requisition must show the name, address, and registration number of the registrant and the number of DEA Forms 222 desired. [21 CFR 1305.11\(c\)](#).

DEA Forms 222 will have an order form number and be issued with the name, address and registration number of the registrant, the authorized activity, and schedules of the registrant. This information cannot be altered or changed by the registrant; the registrant must report any errors to the local [Division Office](#) or the [Registration Section](#) of the Administration to modify the registration. [21 CFR 1305.11\(d\)](#).

5.1.2 Completing DEA Forms 222

The purchaser must prepare and execute a DEA Form 222 by use of a typewriter, computer printer, pen, or indelible pencil. [21 CFR 1305.12\(a\)](#). When ordering schedule II controlled substances, the purchaser is responsible for the following in accordance with [21 CFR 1305.12\(b\)](#):

- Only one item may be entered on each numbered line.
- An item must consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance.
- The number of lines completed must be noted on the DEA Form 222 at the bottom of the form, in the space provided.
- The name and address of the supplier from whom the controlled substances are being ordered. Only one supplier may be listed on any DEA Form 222.
- Each DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign DEA Form 222 under [21 CFR 1305.05](#). The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space.

The purchaser must make a copy of the original DEA Form 222 for its records and then submit the original to the supplier. [21 CFR 1305.13\(a\)](#). Therefore, the purchaser does not have the option of retaining the original. The copy retained by the purchaser may be in paper or electronic form. When the items ordered are received, the purchaser must record on the purchaser's copy of the DEA Form 222 the actual number of commercial or bulk containers of each item received and the date(s) received. [21 CFR 1305.13\(e\)](#).

The purchaser must retain a copy of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached. [21 CFR 1305.17\(a\)](#). The supplier (e.g., compounding NTP) must retain the original of each DEA Form 222 it has filled. [21 CFR 1305.17\(b\)](#).

Under [21 CFR 1305.17\(c\)](#), DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain a copy of the

executed DEA Form 222 and any attached statements or other related documents (not including unexecuted DEA Forms 222, which may be kept elsewhere under [21 CFR 1305.12\(e\)](#), at the registered location printed on the DEA Form 222.

Under [21 CFR 1305.17\(e\)](#), electronic copies of DEA Forms 222 may be stored on a system at a location different from the registered location, provided such copies are readily retrievable at the registered location. Electronic copies of DEA Forms 222 will be deemed to be maintained separately from all other records of the registrant, if copies are readily retrievable separately from all other records.

5.1.3 A Compounding NTP Filling DEA Forms 222

An NTP registered to compound narcotic drugs for off-site use in an NTP is the supplier of a requesting NTP (purchaser). The compounding NTP (supplier) may fill the order, if possible and if the compounding NTP desires to do so, and must record on the original DEA Form 222 its DEA registration number and the number of commercial and bulk containers furnished on each item and the date on which the containers are shipped to the requesting NTP (purchaser). If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the requesting NTP (purchaser). [21 CFR 1305.13\(b\)](#).

The narcotic drugs must be shipped only to the requesting NTP (purchaser) and the location printed by DEA on DEA Form 222. [21 CFR 1305.13\(c\)](#).

The compounding NTP (supplier) must retain the original DEA Form 222 for its records in accordance with [21 CFR 1305.17\(c\)](#). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under 21 CFR [1304.33\(c\)](#) (such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA, either by mail to the Registration Section (see below), or by e-mail to DEA.Orderforms@dea.gov. [21 CFR 1305.13\(d\)](#).

Drug Enforcement Administration
Attn: Registration & Program Support Section/DRR
P.O. Box 2639
Springfield, VA 22152-2639

The copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires. [21 CFR 1305.13\(d\)](#).

5.1.4 Unaccepted and Defective DEA Form 222

A supplier cannot fill a DEA Form 222 if the order form has one of the following problems listed under [21 CFR 1305.15\(a\)](#):

- Not complete;
- Not legible;
- Not properly prepared, executed, or endorsed;
- Shows any alteration, erasure, or change of any description.

If a DEA Form 222 cannot be filled for any reason, the supplier must return the original DEA Form 222 to the purchaser with a statement explaining the reason the order could not be filled (e.g., illegible or altered). [21 CFR 1305.15\(b\)](#). A supplier may refuse to accept an order for any reason as set forth under [21 CFR 1305.15\(c\)](#). If a supplier refuses to accept an order, a statement that the order is not accepted is sufficient. [21 CFR 1305.15\(c\)](#).

Under [21 CFR 1305.15\(d\)](#), when the purchasing NTP receives an unaccepted order, the original DEA Form 222 and the statement must be retained in the files of the purchaser in accordance with [21 CFR 1305.17](#). A defective DEA Form 222 may not be corrected; it must be replaced by a new DEA Form 222 for the order to be filled. [21 CFR 1305.15\(d\)](#).

5.1.5 Lost and Stolen DEA Forms 222

If the purchasing NTP ascertains that an unfilled DEA Form 222 has been lost, the purchasing NTP must execute another and attach a statement containing the order form number and date of the lost form, and stating that the goods covered by the first DEA Form 222 were not received through loss of that DEA Form 222. A copy of the second form and a copy of the statement must be retained with a copy of the DEA Form 222 first executed. A copy of the statement must be attached to a copy of the second DEA Form 222 sent to the supplier. [21 CFR 1305.16\(a\)](#).

If the first DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face “Not accepted” and return the original DEA Form 222 to the purchaser, who must attach it to the statement. [21 CFR 1305.16\(a\)](#).

Whenever any used or unused DEA Forms 222 are stolen or lost (other than in the course of transmission) by any purchaser or supplier, the purchaser or supplier must immediately upon discovery of the theft or loss, report the theft or loss to the Special Agent in Charge of DEA Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost. [21 CFR 1305.16\(b\)](#).

If the theft or loss includes any original DEA Forms 222 received from purchasers and the supplier (e.g., compounding NTP) is unable to state the serial numbers of the DEA Forms 222, the supplier must report the date or approximate date of receipt and the names and addresses of the purchasers. [21 CFR 1305.16\(c\)](#).

If any DEA Forms 222 are lost or stolen, and the purchaser is unable to state the order form numbers of the DEA Forms 222, the purchaser must report, in lieu of numbers of the forms, the date or approximate date of issuance. [21 CFR 1305.16\(d\)](#).

If any unused DEA Form 222 reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the DEA Divisional Office responsible for the area in which the registrant is located must immediately be notified. [21 CFR 1305.16\(e\)](#).

5.1.6 Return of Unused DEA Forms 222

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address as shown on the purchaser's registration) or is suspended or revoked under [21 CFR 1301.36](#) for all schedule I and II controlled substances for which the purchaser is registered, the purchaser must return all unused DEA Forms 222 to the Registration Section (see below). [21 CFR 1305.18](#).

Drug Enforcement Administration
Attn: Registration & Program Support Section/DRR
P.O. Box 2639
Springfield, VA 22152-2639

5.1.7 Cancellation and Voiding of DEA Forms 222

A purchaser may cancel part or all of an order on a DEA Form 222 by notifying the supplier in writing of the cancellation. The supplier must indicate the cancellation on the original DEA Form 222 sent by the purchaser by drawing a line through the canceled items and printing “canceled” in the space provided for the number of items shipped. [21 CFR 1305.19\(a\)](#).

A supplier (e.g., compounding NTP) may void part or all of an order on a DEA Form 222 by notifying the purchaser in writing of the voiding in the manner prescribed for cancellation in 21 CFR 1305.19(a). [21 CFR 1305.19\(b\)](#).

5.2 Controlled Substance Ordering System (CSOS) – Electronic Orders

Any registrant permitted to order schedule II controlled substances may do so electronically via DEA’s CSOS. These records must be maintained electronically for two years. [21 CFR 1305.27](#). CSOS allows for secure electronic transmission of controlled substance orders without the supporting paper DEA Form 222. The use of electronic orders is optional.

The adoption of CSOS standards is the only allowance for the electronic transmission of schedule II controlled substance orders between controlled substance manufacturers, distributors, NTPs, and other DEA authorized entities. CSOS uses Public Key Infrastructure (PKI) technology, which requires CSOS users to obtain a CSOS digital certificate for electronic ordering. The electronic orders must be signed using a digital certificate issued by the Certification Authority (CA) run by DEA. [21 CFR 1305.21\(a\)](#). More information is available on [DEA’s CSOS website](#).

Digital certificates can be obtained only by the person who signed the most recent DEA registration application or renewal application, a person authorized to sign a registration application, or a person granted a POA by a registrant to sign orders for one or more schedules of controlled substances. [21 CFR 1311.10](#). A registrant must appoint a CSOS coordinator who will serve as that registrant’s CSOS coordinator regarding issues pertaining to issuance of, revocation of, and changes to, digital certificates issued under that registrant’s DEA registration. [21 CFR 1311.20\(a\)](#).

A CSOS digital certificate will be valid until the DEA registration under which it is issued expires or until the CSOS CA is notified that the digital certificate should be revoked. [21 CFR 1311.30\(e\)](#) and [1311.40\(a\)](#). CSOS digital certificates will be revoked if the certificate holder is no longer authorized to sign schedule II orders for the registrant, if the information on which the digital certificate is based changes, or if the digital certificate used to sign electronic orders has been compromised, stolen, or lost. [21 CFR 1311.30\(e\)](#) and [1311.40\(a\)](#).

When placing an electronic order, it is important to enter the required information as outlined. [21 CFR 1305.21\(b\)](#). To be valid, the purchaser must digitally sign an electronic order. [21 CFR 1305.21\(a\)](#).

A “Questions and Answers” page and other valuable information about CSOS are available on [DEA’s E-Commerce Program website](#). DEA maintains a support line to assist applicants and subscribers with CSOS issues.

5.2.1 Completing Electronic Orders

Under [21 CFR 1305.21\(a\)](#), the purchaser (e.g., NTP) must sign an electronic order for schedule II controlled substances with a digital signature issued to the purchaser, or the purchaser’s agent, by DEA as provided in [21 CFR Part 1311](#). The following information must be included on an electronic order for schedule II controlled substances in accordance with [21 CFR 1305.21\(b\)](#).

- A unique number the purchaser assigns to track the order in the following format: Last two (2) digits of the year, X, and six (6) characters selected by the purchaser.
- Purchaser’s DEA registration number.
- Name of the supplier.
- Supplier’s complete address (may be completed by the purchaser or the supplier).
- Supplier’s DEA registration number (may be completed by the purchaser or the supplier).
- Date the electronic order is signed.
- The name of the controlled substance product (including the strength where appropriate) or the National Drug Code (NDC) number. The NDC number may be completed by either the purchaser or supplier.
- The quantity in a single package or container.
- The number of packages or containers of each item ordered.

Pursuant to [21 CFR 1305.21\(c\)](#), an electronic order may include controlled substances that are not in schedules I and II and are non-controlled substances.

A purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years. A supplier must retain each original order filled and the linked records for two years. If electronic records are maintained on a central server, the records must be readily retrievable at the registered location. [21 CFR 1305.27](#).

Electronic copies of DEA Forms 222 do not need to be stored on a different server or electronic system from a registrant’s other records. The requirement to store DEA Forms 222 separately from all other records may be met, for electronic copies of DEA Forms 222, by storing them in such a way that they can be readily retrieved separately from all other records. Electronic copies of DEA Forms 222 may be stored on a system at a location different from the registered location, provided such copies are readily retrievable at the registered location. [21 CFR 1305.17\(e\)](#).

Purchasers must be able, during an inspection, to readily retrieve their electronic copies of DEA Forms 222, with any related statements or other documents, and without any other records. [21 CFR 1305.17\(e\)](#); *see* [21 U.S.C. 828\(c\)\(1\)](#).

5.2.2 Unaccepted and Defective Electronic Orders

Under [21 CFR 1305.25\(a\)](#), an electronic order for controlled substances may not be filled if **any** of the following occurs:

- Required data fields have not been completed;
- Order is not signed using a digital certificate issued by DEA;

- Digital certificate used has expired or been revoked prior to signature;
- Purchaser's public key will not validate the digital certificate; or,
- The validation of the order shows that the order is invalid for any reason.

If an order cannot be filled, the supplier must notify the purchaser (e.g., NTP) and provide a statement as to the reason (e.g., improperly prepared or altered). A supplier may, for any reason, refuse to accept an order. If an order is refused, the supplier must notify the purchaser (e.g., NTP) and provide a statement as to why the order was not accepted. A statement that the order is not accepted is sufficient. [21 CFR 1305.25\(b\)](#).

Under [21 CFR 1305.25\(c\)](#), when a purchasing NTP receives an unaccepted electronic order from the supplier, the purchaser must electronically link the statement of non-acceptance to the original order. The original electronic order and the statement must be retained for a period of two years in accordance with [21 CFR 1305.27](#). Neither the NTP nor the supplier may correct a defective order. A new order must be completed for the order to be filled. [21 CFR 1305.25\(d\)](#).

5.2.3 Cancelling and Voiding Electronic Orders

A supplier may void all (or part) of an electronic order by notifying the purchaser (e.g., NTP) of the voiding. If the entire order is voided, the supplier must make an electronic copy of the order, indicate on the copy "Void," and return it to the NTP. The supplier is not required to retain a record of orders that are not filled. [21 CFR 1305.28\(a\)](#). The purchaser must retain an electronic copy of the voided order. [21 CFR 1305.28\(b\)](#).

Should the supplier partially void an electronic order, the supplier must indicate in the linked record that nothing was shipped for each item voided. [21 CFR 1305.28\(c\)](#). The purchaser (e.g., NTP) must, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser must also retain all copies of each unaccepted or defective order and each linked statement. [21 U.S.C. 828\(c\)\(2\)](#) and [21 CFR 1305.27\(a\)](#).

5.2.4 Lost Electronic Orders

If a purchaser (e.g., NTP) determines that an unfilled electronic order has been lost before or after receipt, the NTP must provide, to the supplier, a signed statement containing the unique tracking number and date of the lost order and stating that the goods covered by the first order were not received through loss of that order. [21 CFR 1305.26\(a\)](#). If a new order is executed to replace the lost order, the NTP must electronically link an electronic record of the second order and a copy of the statement with the record of the first order and retain them for two years. [21 CFR 1305.26\(b\)](#) and [21 U.S.C. 828\(c\)\(2\)](#).

If the supplier subsequently receives the lost order, the supplier must indicate that it is "not accepted" and return it to the NTP. The NTP must link the returned order to the record of that order and the statement. [21 CFR 1305.26\(c\)](#).

6. Power of Attorney to Sign DEA Forms 222 and Electronic Orders

A registrant (e.g., NTP) may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Forms 222 or the electronic equivalent by

granting a POA to each such individual. The POA must be available for inspection together with other order records. [21 CFR 1305.05\(a\)](#). The POA is not required to be submitted to DEA.

Pursuant to [21 CFR 1305.05\(d\)](#), the POA must be signed by:

- The registrant, if an individual; a partner of the registrant, if a partnership; or an officer of the registrant, if a corporation, corporate division, association, trust or other entity;
- The person to whom the POA is being granted; and
- Two witnesses.

A POA executed under this section may be signed electronically, by any or all of the persons required to sign. [21 CFR 1305.05\(f\)](#).

A POA may be revoked at any time by the person who signed the most recent application for DEA registration or renewal of registration and two witnesses. [21 CFR 1305.05\(e\)](#).

6.1 Formats for Granting and Revoking a POA:

The POA and notice of revocation must be similar to the following format. [21 CFR 1305.05\(c\)](#).

6.1.1 POA for DEA Forms 222 and Electronic Orders

_____ (Name of registrant)

_____ (Address of registrant)
_____ (DEA registration number)

I, _____ (name of person granting power), the undersigned, who am authorized to sign the current application for registration of the above named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for Forms 222 and to sign orders for schedule I and II controlled substances, whether these orders be on Form 222 or electronic, in accordance with 21 U.S.C. 828 and Part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

(Signature of attorney-in-fact)

Witnesses:

1. _____
2. _____

Signed and dated on the ____ day of _____ in the year ____ at _____.

6.1.2 POA Revocation for DEA Forms 222 and Electronic Orders

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

(Signature of person revoking power)

Witnesses:

1. _____
2. _____

Signed and dated on the ____ day of _____ in the year ____ at _____.

7. Ordering Schedules III – V Controlled Substances

The registrant must keep a receipt (invoice or packing slip) on which it records the date the drugs were received and confirm that the order is accurate. [21 CFR 1304.21\(a\) and \(d\)](#). Pursuant to [21 CFR 1304.22\(c\)](#), such receipts must also contain the following information:

- The name of the substance;
- Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
- The number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from whom the units were acquired;
- The number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed;
- The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the

name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

In addition, these receipts must be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant. [21 CFR 1304.04\(f\)\(2\)](#).

8. Receiving Narcotic Controlled Substances

Federal regulations require that controlled substance deliveries to an NTP be received and secured by the purchasing NTP. [21 CFR 1301.71\(a\)](#), [1301.72\(a\) and \(b\)](#), and [1301.74\(l\)](#). Acceptance of delivery of controlled substances must be made only by a licensed practitioner employed at the NTP or by other authorized individuals designated in writing (excluding persons currently or previously dependent on narcotic drugs), who must sign for the narcotics and place his or her specific title, if any, on the invoice. [21 CFR 1301.74\(h\)](#).

NTPs must maintain a written list of all designated personnel who have been authorized to receive and store controlled substances. [21 CFR 1301.74\(h\)](#). It is recommended that this list be updated whenever a change in designated personnel occurs.

8.1 General Procedures

Under [21 CFR 1304.21\(a\)](#), a registrant must maintain, on a current basis, complete and accurate records of each substance received. Therefore, DEA believes that there are certain required actions – unless noted otherwise as a recommendation – that a designated individual must fulfill when a shipment of narcotic controlled substances is delivered to an NTP:

- Count the number of bottles in the shipment and compare that number with the number indicated on the invoice and the DEA Form 222. [21 CFR 1304.22\(c\)](#), [1305.13\(e\)](#), and [1305.22\(g\)](#).
- For receipt of schedule II narcotic controlled substances, the designated staff member receiving the shipment must complete Part 5 of the purchaser's paper copy of the DEA Form 222 originally completed for the order, annotating the quantity and date received. [21 CFR 1305.13\(e\)](#).
- Each NTP must retain its purchaser's copy of every completed paper DEA Form 222 as part of the NTP's records of receipt for schedule II narcotic controlled substances. All completed paper DEA Form 222s must be maintained separately from all other records and must be retained at the registered location for two years after the date of execution. [21 CFR 1305.17](#). Records of receipt of schedule III-V narcotic controlled substances must also be maintained for two years. [21 U.S.C. 827](#) and [21 CFR 1304.04\(a\)](#).
- If, when checking a shipment of controlled substances at the time of receipt, the NTP's designated staff member receiving the shipment determines that there is an unexplained discrepancy between the amount of medication received and the amount ordered, or if there has been damage to the commercial container/medication, it is recommended that the staff member contact the supplier immediately for further instructions. Consultation with the [local DEA Diversion Field Office](#) and its respective [SOTA](#) may be necessary.

An NTP should also be compliant with all recordkeeping requirements from SAMHSA and its respective [SOTA](#), as these entities may require a longer retention period than two years.

9. Dispensing Narcotic Controlled Substances

This section addresses DEA's regulations for authorized dispensers of narcotic controlled substances utilized by the NTP and how dispensing records must be maintained.

9.1 Authorized Dispensers

In accordance with [21 CFR 1301.74\(i\)](#), narcotic controlled substances dispensed or administered at an NTP must be dispensed or administered directly to patients by the NTP's authorized dispensers:

- Licensed practitioner;
- Registered nurse under the direction of the licensed practitioner;
- Licensed practical nurse under the direction of the licensed practitioner; or
- Pharmacist under the direction of the licensed practitioner.

9.2 Dispensing Records

In accordance with [21 CFR 1304.24\(a\)](#), an NTP must maintain a record of controlled substances dispensed that contains the following information:

- Name, strength, and dosage form of substance;
- Date dispensed;
- Adequate identification of patient;
- Amount consumed;
- Amount and dosage form taken home by patient; and
- Dispenser's initials.

Each NTP must maintain these records in a dispensing log in compliance with [21 CFR 1304.24\(b\)](#) unless the NTP utilizes an automated/computerized data processing system that meets DEA requirements. (See Section 9.3 of this manual).

Records of identity, diagnosis, prognosis, or treatment of any patients, which are maintained in connection with the performance of an NTP, shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by [42 CFR Part 2](#). [21 CFR 1304.24\(d\)](#).

9.3 Computer Software Requirements for Maintaining Dispensing Records

Under [21 CFR 1304.24\(b\)\(1\)](#), as an alternative to maintaining a paper dispensing log for the records required by 21 CFR 1304.24(a) (see Section 9.2 of this manual), an NTP or its mobile component may use a computerized data processing system for the storage and retrieval of the NTP's dispensing records if the following conditions are met:

- The automated system maintains the information required in 21 CFR 1304.24(a);
- The automated system has the capability of producing a hard copy printout of the NTP's

dispensing records;

- The NTP or its mobile component prints a hard copy of each day's dispensing log, which is then initialed appropriately by each person who dispensed medication to the NTP's patients;
- The automated system is approved by DEA;
- The NTP or its mobile component maintain an off-site back-up of all computer-generated NTP information; and
- The automated system is capable of producing accurate summary reports for both the NTP's registered site and any mobile component, for any time-frame selected by DEA personnel during an investigation. If these summary reports are maintained in hard copy form, they must be kept in a systematically organized file located at the NTP's registered site.

Under 21 CFR 1304.24(b)(2), the NTP must retain all records, including those of any mobile component, for two years from the date of execution in accordance with [21 CFR 1304.04\(a\)](#), unless state law requires records be retained longer.

DEA regulations require that NTPs maintain complete and accurate records. [21 CFR 1304.21\(a\)](#). In the event that the computerized recordkeeping system used by an NTP becomes inoperable, it is recommended that each NTP develop an alternate means of maintaining the information outlined in Section 9.2 of this manual (e.g., a hard copy dispensing log) until the computerized recordkeeping system is once again operational.

An NTP may use identification numbers or a similar system instead of patient names for medication dispensing records provided that the NTP maintain an up-to-date cross-index that associates each identification number with the patient's name and address. This list must be readily retrievable for the auditing or verification of program records. [21 CFR 1304.04\(a\)](#) and [21 U.S.C. 827\(a\)](#).

10. Compounding Records

10.1 Records for Compounding for On-Site Use

All NTP sites that compound bulk narcotic solutions from bulk narcotic powder to liquid for on-site use must keep a separate batch record for each compounding, [21 CFR 1304.03\(a\)](#) and [1304.25](#)

10.2 Records for Compounding for Off-Site Use

If an NTP is registered or authorized to compound narcotic drugs for off-site use, the NTP must maintain records that include the following information in accordance with [21 CFR 1304.25](#).

10.2.1 Bulk Form

Records for each narcotic controlled substance in bulk form to be used in, or capable of use in, or being used in, the compounding of the same or other non-controlled substance in finished form must include the following information ([21 CFR 1304.25\(a\)](#)):

- Name of the substance;
- Quantity compounded in bulk form by the NTP, including the date, quantity, and batch or other identifying number of each batch compounded;
- The quantity received from other persons, including the date and quantity received, and name, address, and DEA number of the other person from whom the substance was received;
- Quantity used to compound the same substance in finished form, including

Date and batch or other identifying number of each compounding,

Quantity used in the compound,

Finished form (i.e., 10 mg tablets or 10 mg concentration per fluid ounce),

Number of units of finished form compounded,

The quantity used in quality control,

Quantity lost during compounding and the causes, if known,

Total quantity of the substance contained in the finished form,

Theoretical and actual yields, and

Any other information necessary to account for all controlled substances used in the compounding process;

- The quantity used to manufacture other controlled and non-controlled substances, including the name of each substance manufactured and the information required as listed above;
- Quantity distributed in bulk form to other NTPs, including the date and quantity of each distribution and the name, address, and registration number of each NTP to whom a distribution was made; and,
- Quantity disposed of by destruction, including the reason, date, and manner of each destruction.

For further information on procedures related to the destruction of controlled substances, see Section 13 of this manual.

10.2.2 *Finished Form*

Records for each narcotic substance in finished form must include the following information ([21 CFR 1304.25\(b\)](#)):

- Name of the substance;
- Finished form and the number of units or volume in each commercial container (i.e., 100 tablet bottle or 3 ml bottle);
- Number of containers of each such commercial finished form compounded from bulk form;
- Number of units of finished forms and/or commercial containers received from other persons, including the date or number of units and/or commercial containers in each receipt and the name, address, and DEA registration number of the person from whom the units were received;
- Number of units and/or commercial containers compounded by the NTP from units in finished form received from others, including

Date and batch or other identifying number of each compounding,

Operation performed (i.e., repackaging or relabeling),

Number of units of finished form used in the compounding, the number compounded, and the number lost during compounding, with the causes, if known, and

Any other information necessary to account for all controlled substances used in the compounding process;

- Number of containers distributed to other NTPs, including the date, the number of containers in each distribution, and the name, address, and DEA registration number of the NTP to which the containers were distributed; and,
- Number of units of finished forms and/or commercial containers destroyed in any manner by the NTP including the reason, the date, and manner of destruction.

For further information on procedures related to the destruction of controlled substances, see Section 13 of this manual.

11. Security Requirements for NTPs

Under [21 CFR 1301.71\(a\)](#), all DEA registrants (including NTPs) must provide effective controls and procedures to guard against theft and diversion of controlled substances. DEA will use the security requirements set forth in [21 CFR 1301.71-1301.76](#) as standards to evaluate whether the registrant's security system is compliant.

11.1 General Security Requirements

Before making expenditures for a new or modified security system, the NTP is encouraged to contact the local [DEA Diversion Field Office](#) to determine whether the proposed system complies with DEA regulations. DEA may exercise discretion regarding the degree of security required in an NTP. In determining whether the NTP's overall security system is in compliance with [21 CFR 1301.72-1301.76](#), DEA considers several factors, including but not limited to, the following factors under [21 CFR 1301.71\(b\)](#):

- Type and form of controlled substance handled (e.g., bulk powder, liquid, tablets);
- Quantity of controlled substances handled;
- Location of the facility (e.g., high or low crime area);
- Type of building construction (e.g., brick or frame);
- Type of safe or vault used;
- Adequacy of electronic detection and alarm systems; and
- Availability of local police protection or private security.

In addition to these factors which DEA must consider under its regulations, DEA may exercise discretion and consider other security factors such as the location of the NTP; the number of physicians, staff members and security guards; and the number of patients enrolled in the NTP when evaluating existing security or requiring new security at an NTP. [21 CFR 1301.74\(i\)](#). Also, patients enrolled in an NTP must wait in an area physically separated from the narcotic dispensing and storage areas. [21 CFR 1301.74\(j\)](#).

11.2 Safes, Steel Cabinets, or Vaults

Pursuant to [21 CFR 1301.72\(b\)\(8\)\(i\)](#), schedules III-V controlled substances may be stored with schedules I and II controlled substances under security measures provided by [21 CFR](#)

[1301.72\(a\)](#). These security measures stipulate that where small quantities permit, schedules I and II controlled substances must be stored in a safe or steel cabinet that meets specified criterion under 21 CFR 1301.72(a)(1) or a vault that meets specified criterion under 21 CFR 1301.72(a)(2) or (3). Schedules III-V controlled substances – with no limitation on the quantity to be stored – must be stored in a safe or steel cabinet or vault that meets those same specified conditions. 21 CFR 1301.72(a)(1), (b)(1), and (b)(2).

Requirements for safes and steel cabinets include, but are not limited to, the following specifications or their equivalent:

- Safes and steel cabinets must be constructed to withstand the following:
 - 30 man-minutes against surreptitious entry;
 - 10 man-minutes against forced entry;
 - 20 man-hours against lock manipulation; and
 - 20 man-hours against radiological techniques.
- Safes and steel cabinets that weigh less than 750 lbs. must be bolted or cemented to the floor or wall in such a way that they cannot be readily removed.
- Safes and steel cabinets, if necessary, depending on the quantities and type of controlled substances stored, must be equipped with an alarm system that, upon attempted unauthorized entry, will transmit a signal directly to a central protection company, a police department, or a 24-hour control station operated by the NTP.

Requirements for vaults constructed after September 1, 1971, for schedules I-V controlled substances include, but are not limited to, the following specifications or their equivalent. [21 CFR 1301.72\(a\)\(2\)](#) and [\(b\)\(2\)](#).

- Vaults must be equipped with an alarm system described in section 11.3 below.
- A vault must be constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one-half inch steel rods tied six inches on center, or the structural equivalent.
- The vault door and frame unit must conform to the following specifications or the equivalent:
 - 30 man-minutes against surreptitious entry;
 - 10 man-minutes against forced entry;
 - 20 man-hours against lock manipulation; and
 - 20 man-hours against radiological techniques.
- A vault must be equipped with a self-closing, self-locking day-gate, or its equivalent, if the vault remains open for frequent access.
- The door of the vault is equipped with contact switches.
- The vault must have a device designed to detect illegal entry into the vault (e.g., electrical lacing of the walls, floors and ceilings; sensitive ultrasonic equipment within the vault; or a sensitive sound accumulator system).

NTPs are advised to change security codes and dispensing area locks and keys and lock combinations when dispensing personnel resign or are terminated from employment.

11.3 Alarm Systems

The alarm system for schedules I-V controlled substances stored at an NTP must include alarm

systems designed for safes, steel cabinets, and vaults. [21 CFR 1301.72\(a\)\(1\)\(iii\), \(2\), and \(3\)\(iv\), and \(b\)\(1\) and \(2\).](#)

Vaults, constructed after September 1, 1971, must be equipped with an alarm system that, upon unauthorized entry, will transmit a signal directly to a central station protection company, a police department, or a 24-hour control station operated the NTP. [21 CFR 1301.72\(a\)\(3\)\(iv\) and \(b\)\(2\).](#)

For additional security of staff, patients, and medication, it is recommended, but not required, that components of the alarm systems also include the following security measures:

- A perimeter alarm system covering doors and windows of the NTP; and
- Holdup alarms in strategic areas (i.e., the reception and dispensing areas).

11.4 Accessibility of Controlled Substances

The requirements pertaining to accessibility include the following:

- Only a licensed practitioner or other authorized individual(s) designated in writing (excluding persons currently or previously dependent on narcotic drugs) who are employed at the NTP can accept the delivery of narcotic controlled substances. That person must sign for the narcotics and place his or her specific title (if any) on any invoice. [21 CFR 1301.74\(h\).](#)
- Patients are required to wait in an area physically separated from the narcotic storage and dispensing area(s). [21 CFR 1301.74\(j\).](#)
- Narcotics dispensed or administered at the NTP must be dispensed or administered only by the following individuals:
 - A licensed practitioner;
 - A registered nurse under the direction of a licensed practitioner;
 - A licensed practical nurse under the direction of a licensed practitioner; or
 - A pharmacist under the direction of a licensed practitioner. [21 CFR 1301.74\(i\).](#)
- The narcotic controlled substance storage areas must be accessible only to an absolute minimum of specifically authorized employees. [21 CFR 1301.72\(d\).](#)

The NTP should check with its [SOTA](#), Board of Pharmacy, other state licensing authorities, and [SAMHSA](#) to determine if there are any additional requirements.

11.5 Physical Security Requirements for Compounding

All in-process controlled substances must be returned to the controlled substances storage area at the termination of the compounding process. If the compounding process is not terminated at the end of a workday, the processing area must be securely locked, with adequate security for the area or building. If such security requires an alarm, such alarm, which upon unauthorized entry, must transmit a signal directly to either a central station protection company, a local or state police agency that has a legal duty to respond, or a 24-hour security control station operated by the NTP. [21 CFR 1301.73\(a\).](#)

Manufacturing activities with controlled substances, which include compounding, must be conducted in an area or areas of clearly defined limited access that are under surveillance by an employee or employees designated in writing as responsible for the area. During the production

of controlled substances, the manufacturing areas must be accessible to only those employees required for efficient operation. [21 CFR 1301.73\(b\)](#) and [\(c\)](#).

When it is necessary for maintenance personnel, business guests, or visitors to be present in or pass through the manufacturing areas during production of controlled substances, an employee specifically authorized in writing by the NTP must provide adequate observation of the area. [21 CFR 1301.73\(c\)](#).

11.6 Diversion Control Plan

As outlined in SAMHSA's regulations, a "Diversion Control Plan" is a set of documented procedures that reduces the possibility that controlled substances will be transferred or used illicitly. [42 CFR 8.12\(c\)\(2\)](#). Per SAMHSA regulations, NTPs are required to maintain a Diversion Control Plan in order to reduce the scope of diversion and its impact on communities. See SAMHSA's website for additional information at [Medication-Assisted Treatment \(MAT\) | SAMHSA](#). Or contact SAMHSA [here](#).

11.7 Unsupervised (Take-Home) Doses of Controlled Substances

Pursuant to [21 U.S.C. 823\(g\)\(1\)](#) and [21 CFR 1306.07\(a\)](#), the issuance of a separate DEA registration as an NTP is based on the determination by HHS that the applicant is qualified by HHS standards to engage in narcotic maintenance and/or detoxification treatment and that the NTP will comply with standards respecting the quantities of narcotic drugs to be provided for unsupervised use by the NTP's patients, and that DEA determines that the applicant will secure the stocks of narcotic drugs for such treatment and maintain required records for such treatment. Narcotic addiction treatment medications dispensed to patients for unsupervised use are subject to SAMHSA's requirements in accordance with [42 CFR 8.12\(i\)](#). All applicants and registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances. [21 CFR 1301.71\(a\)](#).

SAMHSA/CSAT's regulations state that part of the criteria the medical director will use in determining whether a patient may be given unsupervised, take-home medication includes an assurance that the unsupervised medication can be safely stored within the patient's home. [42 CFR 8.12\(i\)\(2\)](#). The NTP must ensure that these medications are packaged in a manner that is designed to reduce the risk of accidental ingestion, including the use of childproof containers. [42 CFR 8.12\(i\)\(5\)](#). For those patients who receive individual bottles of liquid methadone, medications should be secured in an inconspicuous, locked container prior to a patient's departure from the NTP. For additional information please reference SAMHSA's [Federal Guidelines for Opioid Treatment Programs](#) and SAMHSA's website at [Medication-Assisted Treatment \(MAT\)](#) SAMHSA.

12. Delivery of Medication to Enrolled NTP Patients (Off-Site)

On June 28, 2021, DEA published the final rule titled, [Registration Requirements for Narcotic Treatment Programs With Mobile Components \(Mobile NTP rule\)](#), 86 FR 33861. DEA regulations do not currently address other off-site delivery options of narcotic controlled substances approved by FDA for the treatment of opioid use disorder (OUD) to enrolled patients

at an unregistered, off-site location. However, it is DEA's policy² that other options mentioned in this section may also be conducted as long as the NTP is compliant with the CSA, DEA regulations, SAMHSA regulations, and SOTA requirements. Contact [SAMHSA](#) and your [SOTA](#) regarding this matter.

12.1 Mobile Narcotic Treatment Vans

DEA's Mobile NTP rule revised DEA regulations to waive the requirement of a separate registration³ for DEA-registered NTPs that utilize mobile components for dispensing under certain conditions, and such associated components are considered a coincident activity permitted under the NTP's registration.⁴ Specifically, DEA-registered NTPs would be allowed to operate mobile components (in the State in which the registrant is registered) to dispense narcotic drugs in schedules II–V at remote location(s) for the purpose of maintenance or detoxification treatment as long as they fully comply with the requirements set forth in the Mobile NTP rule. DEA noted that, “except where otherwise provided for by [its] rule or other laws or regulations, mobile NTPs are subject to the same standards as the NTPs of which they are a part.” 86 FR 33861, 33874.

For any NTP intending to operate a mobile NTP, the registrant must notify the local DEA office, in writing, of its intent to do so, and the NTP must receive explicit written approval from the local DEA office prior to operating the mobile NTP. The mobile NTP may only operate in the same State in which the NTP is registered. [21 CFR 1301.13\(e\)\(4\)](#).

An NTP's motor vehicle(s) must possess valid county/city and State information (e.g., a vehicle information number (license plate number) on file at the registered location of the NTP and provide proper city/county and State licensing and registration to DEA at the time of inspection, and prior to transporting controlled substances away from the NTP's registered location. [21 CFR 1301.13\(e\)\(4\)\(i\)](#).

A mobile NTP may operate at any remote location or locations within the same State as its registered location, including correctional facilities, so long as doing so is otherwise consistent with applicable Federal, State, tribal, and local laws and regulations, and so long as the local DEA office, when notified as specified, does not otherwise direct. [21 CFR 1301.13\(e\)\(4\)\(iii\)](#). A mobile NTP is not permitted to reverse distribute, share, or transfer controlled substances from one mobile component to another while away from the registered location; is not allowed to act as a collector under 21 CFR 1301.51 and 1317.40; and may not function as a hospital, LTCF, or emergency medical service vehicle, and will not transport patients. [21 CFR 1301.13\(e\)\(4\)\(ii\)](#).

A mobile NTP must meet DEA's physical security requirements to include a safe installed to store schedules II-V narcotic drugs for the purpose of maintenance and detoxification treatment and an alarm system that meets requirements set forth in 21 CFR 1301.72(a)(1). The storage area for controlled substances must conform to the accessibility requirements set forth in 21 CFR

² Guidance documents, like this document, are not binding and lack the force and effect of law, unless expressly authorized by statute/regulation or expressly incorporated into a contract, grant, or cooperative agreement.

³ Generally, all persons required to register under the CSA must obtain a separate registration at “each principal place of business or professional practice” where such persons manufacture, distribute, or dispense a controlled substance. 21 U.S.C. 822(e)(1).

⁴ These revisions were intended to make maintenance or detoxification treatments for OUD more widely available, while ensuring that safeguards are in place to reduce the likelihood of diversion. 86 FR 33861, 33862.

1301.72(a)(1)(iii) and not be accessible from outside the vehicle. During transport all controlled substances must be properly secured in the safe. Upon completion of operation, the mobile NTP must immediately return to the registered location, and all controlled substances removed from the conveyance and secured within the registered location. All NTPs with mobile components must establish standard operating procedures to ensure, if the mobile component becomes inoperable, that all controlled substances are accounted for, removed, and secured at the registered location. [21 CFR 1301.72\(e\)\(1\)](#). See also the other security requirements for mobile NTPs under [21 CFR 1301.74\(i\) - \(n\)](#).

12.2 Correctional Facilities

As discussed in section 12.1 above,

A mobile NTP may operate at correctional facilities within the same State as its registered location so long as doing so is otherwise consistent with applicable Federal, State, tribal, and local laws and regulations, and so long as the local DEA office, when notified as specified, does not otherwise direct. [21 CFR 1301.13\(e\)\(4\)\(iii\)](#).

Absent a mobile component of an NTP, a correctional facility may provide FDA-approved narcotic drugs specifically for the treatment of narcotic addiction by any of the options outlined below.

- A correctional facility may transport inmates to the NTP at which they are enrolled as patients to receive their medication in accordance with [SOTA](#) and [SAMHSA](#) requirements.
- Staff employed by the correctional facility may take custody from the NTP of a locked container that holds patient-specific medications. The transporting staff, who should not have a key to the locked container, will deliver the medication to the facility and hand off to its nursing staff. The NTP and the facility need to implement controls to prevent diversion, including chain of custody documentation and appropriate secure storage that complies with state laws. The facility personnel who dispense or administer the medication to the inmate must fit into one of the four categories set forth in [21 CFR 1301.74\(i\)](#). Each of the facility staff who transport or dispense the medication should be made an agent of the NTP through a formal written agreement. [21 U.S.C. 802\(3\)](#).
- A practitioner may register with DEA as an NTP at a correctional facility. [21 U.S.C. 823\(g\)\(1\)](#) and [21 CFR 1306.07\(a\)](#).
- A correctional facility may register with DEA as a hospital/clinic. [21 U.S.C. 802\(21\)](#), [21 U.S.C. 822\(a\)\(2\)](#), [21 U.S.C. 823\(f\)](#), [21 CFR 1301.11\(a\)](#). Under a hospital/clinic registration, a physician or authorized hospital staff may administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an **incidental adjunct** to medical or surgical treatment of conditions other than addiction. [21 CFR 1306.07\(c\)](#).
- A DEA-registered physician who is not specifically registered to conduct an NTP may administer up to three days of narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time, and may not be renewed or extended. [21 CFR 1306.07\(b\)](#). The

physician must be registered at the location where the controlled substances are maintained and administered. [21 U.S.C. 822\(a\)\(2\)](#), [21 U.S.C. 823\(f\)](#), [21 CFR 1301.11\(a\)](#).

- A qualifying practitioner under [21 U.S.C. 823\(g\)\(2\)\(G\)\(iii\)](#) who has received a waiver from registration in accordance with the Drug Addiction Treatment Act of 2000 (DATA) may administer, dispense, or prescribe FDA-approved schedules III-V narcotic drugs. [21 U.S.C. 823\(g\)\(2\)](#) and [21 CFR 1306.07\(d\)](#). If a qualifying practitioner procures stock, the qualifying practitioner must be registered at the location where the narcotic drugs are maintained and administered. [21 U.S.C. 822\(a\)\(2\)](#), [21 U.S.C. 823\(f\)](#), [21 CFR 1301.11\(a\)](#) A qualifying practitioner under [21 U.S.C. 823\(g\)\(2\)\(G\)\(iii\)\(I\)](#) (i.e., a qualifying physician) and (II) (i.e., qualifying other practitioner) may only do so if permitted by state law.

12.3 Long Term Care Facilities

Although DEA did not explicitly state in its Mobile NTP rule that a mobile component may stop at a long term care facility (LTCF), DEA regulations do not prohibit an NTP's mobile component from doing so. See the prior section regarding MAT options absent a mobile NTP component as they also apply to LTCFs.

12.4 Alcohol Treatment Center (ATC) or Behavioral Health Facility

Although DEA did not explicitly state in its Mobile NTP rule that a mobile component may stop at an alcohol treatment center (ATC) or behavioral health facility for the NTP's enrolled patients, DEA regulations do not prohibit an NTP's mobile component from doing so. See [Section 12.2](#) regarding MAT options absent a mobile NTP component as they also apply to ATCs and behavioral health facilities.

12.5 Home-Bound Patients

Although DEA did not explicitly state in its Mobile NTP rule that a mobile component may stop at the address of an enrolled home-bound patient, DEA regulations do not prohibit an NTP's mobile component from doing so.

13. Theft, Loss, Disposal, or Transfer of Controlled Substances

The following section addresses the procedures for an NTP to follow in case of theft, loss, disposal, or transfer of controlled substances held on its controlled premises.

13.1 Theft or Loss of Controlled Substances

An NTP must notify its local [DEA Diversion Field Office](#) in writing within one business day of discovery of a theft or significant loss of a controlled substance. [21 CFR 1301.74\(c\)](#). An NTP should also notify local law enforcement and state regulatory agencies. If there is a question as to whether a theft has occurred or a loss is significant, the NTP should report it to DEA and the appropriate state and local authorities.

There is no single objective standard that can be established and applied to all NTPs to determine

whether a loss is significant. Any unexplained loss or discrepancy should be reviewed within the context of an NTP's business activity and environment. What constitutes a significant loss for one NTP may be construed as comparatively insignificant for another.

When determining whether a loss is significant, the NTP should consider, among others, the following factors ([21 CFR 1301.74\(c\)](#)):

- What the actual quantity of controlled substances lost is in comparison to the type of business;
- The specific controlled substances lost;
- Whether the loss of the controlled substances can be associated with access by specific individuals or can be attributed to unique activities that may take place involving the controlled substances;
- If there is a pattern of losses over a specific time period or whether the losses appear to be random; and what the results of efforts taken to resolve the losses are;
- If known, whether the specific controlled substances are likely candidates for diversion;
- Local trends and other indicators of the diversion potential of the missing controlled substances.

The DEA Form 106 (Report of Theft or Loss of Controlled Substances) is used to document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved. An electronic version of the DEA Form 106 is available and can be accessed at www.DEAdiversion.usdoj.gov. The online version of the DEA Form 106 may be modified at any time. (See Appendix D for detailed instructions for completing DEA Form 106.) If using the paper version, the registrant must send the original DEA Form 106 to his or her local [DEA Diversion Field Office](#) and keep a copy for his or her records. [21 CFR 1301.74\(c\)](#) and general instructions on DEA Form 106.⁵ The paper version of the form can be obtained by writing to the following address:

Drug Enforcement Administration
Attn: Regulatory Section (DRG)
8701 Morrisette Drive
Springfield, VA 22152-2639

If, after notifying DEA, the registrant determines that no such theft or loss of controlled substances has occurred, a DEA Form 106 does not need to be filed. However, DEA should be notified of this fact in order to resolve the initial report and explain why no DEA Form 106 will be filed.

13.2 In-Transit Loss of Controlled Substances

When all or part of a shipment of controlled substances fails to reach its intended destination, the supplier is responsible to report the in-transit loss of controlled substances to DEA. [21 CFR 1301.74\(c\)](#). As the purchaser, the NTP is responsible for reporting any loss of controlled substances after it has signed for or taken custody of a shipment. If the NTP does not take custody of the shipment and instead returns it to its supplier, it is the supplier's responsibility to

⁵ On July 29, 2020, DEA published in the Federal Register the Notice of Proposed Rulemaking titled, "[Reporting of Theft or Significant Loss of Controlled Substances, \(85 FR 45547\)](#)". If this rule is finalized as proposed, then DEA registrants will be required to submit DEA Form 106 electronically to the DEA within a 15-day time period.

report any loss of controlled substances in the original shipment. All in-transit losses must be reported. [21 CFR 1301.74\(c\)](#).

If there is a discrepancy between the amount of controlled substances received and the amount ordered (i.e., a discrepancy that has not been explained by the supplier on the invoice included with the delivered order), the NTP should contact its supplier immediately for further instructions. When receiving a shipment, if the NTP determines there was damage to the controlled substances, the NTP should contact its supplier immediately.

13.3 Breakage and Spillage of Controlled Substances

Every registrant required to keep records must maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her. [21 U.S.C. 827\(a\)\(3\)](#) and [21 CFR 1304.21\(a\)](#).

While neither the CSA nor DEA's regulations specifically address the breakage and/or spillage of controlled substances, DEA offers the following guidance. The witnessed breakage or spillage of a controlled substance does not constitute a loss of controlled substances because the substances can be accounted for. In circumstances where there is breakage, spillage, or other damage to controlled substances, and the controlled substances are still recoverable, the NTP should dispose of the controlled substances in accordance with [21 CFR 1317.05\(b\)](#) and [1304.21\(e\)](#).

If the breakage or spillage is clearly observed, but the controlled substances are not recoverable, the NTP should document the circumstances of the event in their inventory records and signed by two individuals who can testify that a breakage or spillage occurred. [21 CFR 1317.95\(d\)](#). These records must be maintained in the NTP's files for a minimum of two years. [21 U.S.C. 827\(b\)](#) and [21 CFR 1304.04\(a\)](#).

13.4 Improper Use of DEA Form 106

The DEA Form 106 should be used only to document thefts or significant losses of controlled substances. DEA has stressed that registrants, should not report to DEA, or record on a DEA Form 106, minor inventory discrepancies, not attributable to theft, in attempts to balance their books. See [68 FR 40576, 40577, July 8, 2003](#). An NTP should make appropriate notations of minor inventory discrepancies, indicating the amount of variance between the physical count and the amount accounted for thorough records. Such discrepancies need not be reported to DEA if they are not significant or actual losses. If an NTP is unsure of the significance of a loss after considering the factors described above, it should file a DEA Form 106.

Any continuing pattern of loss that appears seemingly to be random or insignificant in quantity should always be considered significant. See [21 CFR 1301.74\(c\)\(4\)](#).

13.5 Disposal of Controlled Substances

In accordance with [21 CFR 1317.05\(b\)](#), an NTP (a registered non-practitioner) that is in lawful possession of a controlled substance inventory must dispose of the inventory in one of the following ways:

- Promptly destroy the controlled substance in accordance with [21 CFR 1317, subpart C](#)

using an on-site method of destruction rendering the controlled substances to a [non-retrievable](#) state;

- Promptly deliver the controlled substance to a reverse distributor's registered location by common or contract carrier or by reverse distributor pick-up at the registrant's registered location;
- For the purpose of return or recall, promptly deliver the controlled substance by common or contract carrier or pick-up at the registrant's registered location to one of the following:
 - the registered person from whom it was obtained,
 - the registered manufacturer of the substance, or
 - another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf;
 - See [Section 13.7 of this manual](#).
- Promptly transport the controlled substance by its own means to the registered location of a reverse distributor, the location of destruction, or the registered location of any person authorized to receive the controlled substance for the purpose of return or recall as described in subparagraph (b)(3) (the above bullet point) and in accordance with the following requirements.
 - If transporting controlled substances by its own means to an unregistered location for destruction, it must be done in accordance with the procedures set forth under [21 CFR 1317.95\(c\)](#).
 - If transporting controlled substances by its own means to a registered location for any authorized purpose, transportation must be directly to the authorized registered location and two employees of the transporting non-practitioner registrant must accompany the controlled substances to the registered destination location. Directly transported means the substances shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration must not occur.

Destruction procedures of any controlled substance must be in accordance with the requirements under [21 CFR 1317.95](#).

When an NTP utilizes the services of a DEA-registered reverse distributor to transfer schedule II controlled substances for the purpose of destruction, the reverse distributor and the NTP become the purchaser and supplier, respectively. As such, the reverse distributor must issue a DEA Form 222 to the NTP for the distribution of the controlled substances. [21 CFR 1305.03](#) and [1317.10\(b\)](#). When an NTP utilizes the services of a DEA-registered reverse distributor to transfer schedules III-V controlled substances for the purpose of destruction, the NTP must generate a record of distribution that lists the number of units of finished form and/or commercial containers distributed or disposed of in any other manner by the NTP, including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed. [21 CFR 1304.22\(a\)\(2\)\(ix\)](#) and [1304.22\(c\)](#). An NTP must maintain copies of the records documenting the transfer of the controlled substances for a period of two years. [21 U.S.C. 827\(b\)](#).

An NTP is not required to generate a DEA Form 41 (Registrants Inventory of Drugs Surrendered) regarding the transfer of controlled substances to a DEA registered reverse distributor. Rather, the reverse distributor who is registered with DEA is responsible for

generating and maintaining the DEA Form 41. See [21 CFR 1304.21\(e\)](#).

DEA procedures established for the disposal of controlled substances should not be construed as circumventing in any way other federal, state, local or tribal laws or regulations for the disposal of controlled substances.

The NTP is not eligible to dispose of controlled substance inventory using local drop boxes or during prescription drug take-back events established for the general public.

13.6 NTPs as Authorized Collector Sites for Drug Disposal

On September 9, 2014, DEA published a Final Rule titled “[Disposal of Controlled Substances](#)” which, among other things, established a provision at 21 CFR 1317.40, authorizing an NTP that has modified its DEA registration to collect expired or unwanted controlled substances from patients at the NTP’s registered location. 79 FR 53520. To become an authorized collector, an NTP can modify its registration for free online at www.DEAdiversion.usdoj.gov. [21 CFR 1301.51\(b\)](#).

NTPs that are authorized collectors must maintain collection receptacle(s) at their registered facilities where it must be located in a room that does not contain any other controlled substances and is securely locked with controlled access. [21 CFR 1317.75\(d\)\(2\)\(ii\)](#). Authorized collectors may collect pharmaceutical controlled substances from ultimate users through collection receptacles. However, NTPs are not allowed to modify their registrations to authorize their mobile components to act as collectors. [21 CFR 1301.13\(4\)\(ii\)](#).

Should an NTP desire to be a collection point only for patients registered to that NTP, the NTP can opt not to be included on the Diversion Control Division’s Year Round Pharmaceutical Locations search portal’s published list on its [Drug Disposal Information](#) webpage. This may be done by the NTP through the [Registration for Disposal of Controlled Substances](#) secure portal on the [Drug Disposal Information webpage](#) (a link to the portal is also on Diversion’s [Registration webpage](#)), or by contacting a DEA [Diversion Registration Specialist](#) at one of our call centers or locally.

DEA-registered NTPs may modify their registration to become authorized collectors. [21 CFR 1301.51\(b\)](#). An NTP may install a collection receptacle for the collection of schedules II-V controlled substances. 21 CFR 1317.75(b). The NTP shall only allow ultimate users and other authorized non-registrants in possession of a controlled substance in schedules II-V to deposit such substances under [21 CFR 1317.75\(c\)](#). Sealed inner liners from collection receptacles must be stored in accordance with schedule I and II controlled substances under [21 CFR 1301.72\(a\)](#).

Authorized collectors are not allowed to conduct community take-back events without the participation and presence of law enforcement personnel. [21 CFR 1317.65\(a\)](#) and (b). The required security measures outlined in 21 CFR [1317.60](#) and [1317.75](#) apply to all collection receptacles. Other reporting and recordkeeping requirements under [21 CFR part 1304](#) (1304.03(a), 1304.11(e)(7), 1304.21, 1304.22(f)) and [21 CFR 1305.03\(f\)](#) ([See Section 5 of this manual](#) for further information regarding DEA Forms 222) also apply to collection activities. NTPs are not required to become authorized collectors.

Only ultimate users themselves can put the controlled substances directly into the on-site collection receptacle at an authorized NTP facility. See [21 CFR 1317.75\(c\)](#). The on-site collection receptacle must meet the following design specifications under [21 CFR 1317.75\(e\)](#):

- Be securely fastened to a permanent structure;
- Be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner as specified in [21 CFR 1317.60](#);
- The outer container must include a small opening that allows for contents to be added but not removed;
- The outer container must prominently display a sign stating only schedule II-V controlled substances and non-controlled substances are acceptable substances.

Regarding the installation and removal of the inner liner, these activities must be performed by or under the supervision of at least two employees of the authorized collector. [21 CFR 1317.75\(g\)](#).

An NTP can partner with an authorized reverse distributor who conducts a mail-back program by providing empty mail-back packages to patients. This does not require an NTP to modify its DEA registration and there are no recordkeeping requirements. [21 CFR 1317.70\(c\)](#).

An NTP that is authorized to place a collection receptacle in its registered location must maintain the following inner liner records in accordance with [21 CFR 1304.22\(f\)\(2\)](#):

- Date each unused inner liner was acquired and the unique identification number (UIN) and size (e.g., 5-gallon, 10-gallons, etc.) contained on the outside of each inner liner.
- Date each inner liner is installed in a collection receptacle, the address of the location at which each inner liner is installed, the UIN and size of each installed inner liner, the registration number of the NTP, and the names and signatures of the two NTP employees that witnessed each installation.
- Date each inner liner is removed from a collection receptacle and sealed, the address of the location at which each inner liner is removed, the UIN and size of each removed inner liner, the registration number of the NTP, and the names and signatures of the two NTP employees that witnessed each removal.
- Date each sealed inner liner is transferred to storage, the UIN and size of each sealed inner liner stored, and the names and signatures of the two NTP employees that transferred each sealed inner liner to one of the following applicable storage areas (see Section 11.2 of this manual):
 - Where small quantities permit, a safe or steel cabinet; or
 - A vault.
- Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor to whom each sealed inner liner was transferred, the UIN and size of each sealed inner liner transferred, and the names and signatures of the two NTP employees that transferred each sealed inner liner to the reverse distributor.
- NTPs must report the theft or loss of sealed inner liners as they would the theft or loss of other controlled substances. (See [Section 13.1 of this manual](#)).

13.7 Transfer to the Original Supplier or Original Manufacturer

An NPT, as a non-practitioner registrant, has four methods for disposing of a controlled substance in its lawful possession. See [21 CFR 1317.05\(b\)](#). For the purpose of return or recall, under subparagraph (3), an NPT must transfer controlled substances to its original supplier, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf. DEA recommends that an NPT contact the appropriate entity prior to the transfer. Regarding recordkeeping requirements for registrant return or recall transactions, the following provisions under [21 CFR 1317.10\(a\) and \(b\)](#) apply:

- Each registrant must maintain a record of each return or recall transaction in accordance with [21 CFR 1304.22\(a\)\(2\)\(iv\)](#).
- Each registrant that delivers a controlled substance in schedule I or II for the purpose of return or recall must use an order form in accordance with [21 CFR part 1305](#). (See also [Section 5 of this manual](#)).

14. Emergency Preparedness

For NTPs requiring assistance with controlled substances or their DEA registrations in response to domestic disasters such as hurricanes, earthquakes, floods, and tornadoes, **inside** the U.S., DEA's Diversion Control Division has established a link for emergency requests at [DEA Emergency Disaster Relief](#).

An NTP registrant can access this link by clicking on the [Emergency Disaster Relief](#) icon on the lower left-hand side of DEA's [Diversion Control Division homepage](#) if in need of immediate assistance by DEA, such as to change a physical location for the NTP; authorize a shipment of controlled substances without a DEA Form 222; or, approve temporary security measures during a national disaster/emergency situation.

An NTP should send an e-mail to Natural.Disaster@dea.gov with the name of the NTP (as it appears on the DEA Registration), the DEA registration number, the name and contact information of the person making the request, and the nature of the emergency request. DEA has specifically designated staff members who will be notified automatically and will respond. Indicate on e-mail subject line **Domestic Request** and include the following information:

- Registrant name;
- DEA Registration number; and
- Contact information: office telephone number, cellular telephone number, e-mail address, facsimile number.

Requests for DEA emergency authorization involving controlled substances are relayed through this website 24 hours a day/7 days a week.

14.1 Other Emergency Situations

In the event an emergency situation occurs which impedes the NTP from providing narcotic treatment to its patients, the NTP should follow the guidelines as submitted to its [SOTA](#) and accreditation authorities. The NTP should also contact its [local DEA Diversion Field Office](#).

Appendix A: Definitions

The following definitions may be found in the CSA ([21 U.S.C. 802](#)), DEA regulations ([21 CFR 1300.01\(b\)](#) or [1300.05\(b\)](#)), or SAMHSA regulations unless otherwise indicated below.

Administer

The direct application of a controlled substance to the body of a patient or research subject by a practitioner (or, in their presence, by their authorized agent) or a patient or research subject at the direction and in the presence of the practitioner, whether such application be by injection, inhalation, ingestion, or any other means.

Compounder

Any person engaging in maintenance or detoxification treatment who also mixes, prepares, packages, or changes the dosage form of a narcotic drug listed in schedule II-V for use in maintenance or detoxification treatment by another NTP.

Controlled Premises

Places where original or other records or documents required under the CSA are kept or are required to be kept, and places, including factories, warehouses, and other establishments, and conveyances, where persons registered under the CSA (or exempt from registration under the CSA or by DEA regulation) or regulated persons may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained. [21 CFR 1316.02\(c\)](#) and [21 U.S.C. 880\(a\)](#)

Detoxification Treatment

The dispensing of a narcotic drug(s) in decreasing doses to an individual to alleviate adverse physiological or psychological effects due to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within a specified period of time. Short-term detoxification treatment is for a period not more than 30 days; long-term detoxification is for a period more than 30 days but not more than 180 days.

Dispense

To deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term “dispenser” means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

Distribute

To deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term “distributor” means a person who so delivers a controlled substance or a listed chemical.

Long Term Care Facility

A nursing home, retirement care, mental care or other facility or institution that provides extended health care to resident patients.

Maintenance Treatment

The dispensing for a period longer than 21 days of a narcotic drug(s) in the treatment of an individual for dependence upon heroin or other morphine-like drug.

Medication Unit

A facility established as part of, but geographically separate from, an opioid treatment program from which licensed practitioners and community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis. [42 CFR 8.2](#). Although DEA regulations do not specifically address the term “medication unit,” they do define the term “narcotic treatment program.” See below. As DEA regulations currently do not differentiate between an NTP and a medication unit, an NTP registration pursuant to [21 CFR 1301.13\(e\)\(1\)\(vii\)](#) is required to operate a medication unit.

Narcotic

Any of the listed substances under [21 U.S.C. 802\(17\)](#) and [21 CFR 1300.01\(b\)](#), whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis.

Narcotic Treatment Program

A program engaged in maintenance and/or detoxification treatment with narcotic drugs.

Non-Retrieveable

For the purpose of destruction, the condition or state to which a controlled substance is rendered following a process that permanently alters that controlled substance’s physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes.

On-Site

Located on or at the physical premises of the registrant’s registered location.

Practitioner

A physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he or she practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

Prescription

An order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

Qualifying Practitioner

For the purposes of this manual, a Qualifying Practitioner (also known as a qualifying physician) is a physician who meets the requirements of the DATA to administer, dispense, or prescribe narcotic drugs in schedule III-V, or a combination of such drugs, approved by FDA specifically

for use in narcotic maintenance or detoxification treatment. [21 U.S.C. 823\(g\)\(2\)\(G\)\(iii\)\(I\)](#).

Qualifying Other Practitioner

A nurse practitioner or a physician assistant, or with a sunset provision ending on October 1, 2023, a clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife who meets the requirements of the DATA to prescribe narcotic drugs in schedule III-V, or a combination of such drugs, approved by FDA specifically for use in narcotic maintenance or detoxification treatment. [21 U.S.C. 823\(g\)\(2\)\(G\)\(iv\)](#).

Readily Retrievable

Records that are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Ultimate User

A person who has lawfully obtained, and who possesses, a controlled substance for his or her own use or for the use of a member of his or her household or for an animal owned by him or her or by a member of his or her household.

Appendix B: Unscheduled On-Site DEA Inspections

DEA is authorized in accordance with the CSA ([21 U.S.C. 880\(b\)](#)) and DEA's implementing regulations ([21 CFR Part 1316.03, unless otherwise noted](#)) to enter "controlled premises" and conduct administrative inspections thereof, for the purpose of:

- 1) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under the CSA and DEA regulations, including, but not limited to, inventory and other records required to be kept under [21 CFR Part 1304](#), order forms required to be kept under [21 CFR Part 1305](#), and prescription and distribution records required to be kept under [21 CFR Part 1306](#).
- 2) Inspecting within reasonable limits and in a reasonable manner all pertinent equipment, finished and unfinished controlled substances, listed chemicals, and other substances or materials, containers, and labeling found at the controlled premises relating to the CSA.
- 3) Making physical inventory of all controlled substances and listed chemicals on hand at the premises.
- 4) Collecting samples of controlled substances or listed chemicals and providing a receipt for such samples on a DEA Form 400 (Receipt for Samples) to the owner, operator, or agent in charge of the controlled premises.
- 5) Checking records and information on distribution of controlled substances or listed chemicals.
- 6) Unless the owner, operator, or agent in charge of the controlled premises so consents in writing, no inspection shall extend to financial, sales, or pricing data. [21 CFR 1316.04\(a\)](#). All other things (including records, files, papers, processes, controls and facilities) appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the CSA and DEA regulations may be inspected.

In accordance with [21 CFR 1316.05](#), authorized DEA personnel shall state their purpose, and present appropriate credentials and a written notice of inspection DEA Form 82 (Notice of Inspection of Controlled Premises) authority under [21 CFR 1316.06](#) to the owner, operator, or agent in charge of the premises. Upon receiving informed consent, authorized DEA personnel under [21 CFR 1316.08](#) or through the use of an administrative warrant issued under [21 CFR 1316.09 – 1316.13](#), shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner. The NTP may be asked to provide information, records, and other documents to investigators. These items may include but are not limited to the following:

- Documentation of his or her DEA registration number/UIN (Unique Identification Number) issued in accordance with the DATA;
- Proof of valid medical and state licensure;
- Treatment logs;
- Receipt records;
- Dispensing records;
- Inventory (initial and biennial); and,
- Security compliance measures.

Appendix C: DEA Forms

Form Number	Title
<u>DEA Form 41</u>	Registrant Record of Controlled Substances Destroyed
<u>DEA Form 106</u>	Report of Theft or Loss of Controlled Substances
<u>DEA Form 222</u>	Official Order Form for Schedule I and II Controlled Substances
<u>DEA Form 223</u>	Certificate of Registration
<u>DEA Form 363</u>	Application for Registration under the Narcotic Addict Treatment Act of 1974

Appendix D: Guidelines for Completing the DEA Form 106

Instructions for completing the DEA Form 106 are provided when filling out either the hard copy or the electronic version of the form. Listed below are additional guidelines:

- Do not use a DEA Form 106 to report an accidental spillage. Save the broken bottles, salvage the product if possible, and contact the local [DEA Diversion Field Office](#) for additional instructions. (See [Section 13.3 of this manual](#).)
- Miscounts or adjustments to inventory involving clerical errors should not be reported on a DEA Form 106. A separate log documenting the discrepancies may be kept at the NTP's discretion.

The following guidelines apply only if the NTP is using the hard copy version of the DEA Form 106:

- If thefts have occurred due to employee pilferage over a period of time, document on the DEA Form 106 the date of discovery. Provide estimated beginning and ending dates of the thefts in the comment section with an explanation.
- Enter the number of thefts or losses experienced in the last 24 months, but do not include the current theft or loss being reported. If the current theft or loss was the only theft or loss in the last 24 months, enter "0" (zero).
- Enter the amount paid for the controlled substances.
- If a receipt of the controlled substance(s) was accepted before discovering a loss in transit, identify the supplier and its DEA registration number.
- When explaining how many losses occurred from the same carrier, do not include the current loss.
- The date next to the signature and title should be the date the form was completed and transmitted to DEA.
- If amending a paper version of a prior DEA Form 106, print "amended" in the upper front page margin, with the date of the theft.

Appendix E: Additional Assistance including Internet Resources

This manual is intended to provide guidance and information on the requirements of the CSA and its implementing regulations. Additional clarification or assistance may be obtained at the local [DEA Diversion Field Offices](#); the local office also can receive comments on any matter regarding DEA's requirements or regulatory activities. Every effort will be made to respond promptly to each inquiry.

Plain Language

DEA has made every effort to write this manual in clear, plain language. Suggestions as to how to improve the clarity of this manual may be sent to the following contact information:

Drug Enforcement Administration
Diversion Control Division
Attn: Policy Section/DPY
8701 Morrisette Drive
Springfield, VA 22152
Telephone: 202-307-7297

Internet Resources

DEA, Diversion Control Division
www.DEAdiversion.usdoj.gov

DEA Homepage
www.DEA.gov

U.S. Government Publishing Office
www.govinfo.gov/

Electronic Code of Federal Regulations, Title 21, Chapter II
www.ecfr.gov

Office of National Drug Control Policy
www.whitehousedrugpolicy.gov

Food and Drug Administration
www.FDA.gov

SAMHSA
www.SAMHSA.gov

CSAT Buprenorphine Information Center
<http://buprenorphine.samhsa.gov>

Federation of State Medical Boards
www.FSMB.org

National Association of State Controlled Substances Authorities
www.NASCSA.org

Appendix F: National Small Business and Agriculture Regulatory Ombudsman

The Small Business Regulatory Enforcement Fairness Act of 1996 established the National Small Business and Agriculture Regulatory Ombudsman and 10 Regional Fairness Boards to receive comments from small businesses about federal agency enforcement actions. The Ombudsman annually evaluates enforcement activities and rates each agency's responsiveness to small business. Comments on DEA enforcement actions may be submitted to the Ombudsman at 1-888-REG-FAIR (1-888-734-3247).